

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

ANTHONY BUZZELLI AND LORRAINE
BUZZELLI,

Plaintiff,

v.

NOVARTIS PHARMACEUTICALS
CORPORATION,

Defendant.

Case No. 2:20-cv-00425

The Hon. Arthur J. Schwab

ELECTRONICALLY FILED

Fed. R. Civ. P. 26(f) REPORT OF THE PARTIES

Counsel for the parties and unrepresented parties shall confer regarding the matters identified herein and prepare a signed report in the following form to be filed at least 21 days before the Initial LCvR 16.1 Scheduling Conference or at such other time as ordered by the court. This report form may be downloaded from the Court's website as a word-processing document and the information filled in as requested on the downloaded form. The dates to be provided in the report are suggested dates and may be accepted or modified by the Court.

1. Identification of counsel and unrepresented parties. Set forth the names, addresses, telephone and fax numbers and e-mail addresses of each unrepresented party and of each counsel and identify the parties whom such counsel represent:

Christopher R. LoPalo
W. Steven Berman
Napoli Shkolnik PLLC
1 Greentree Centre
10,000 Lincoln Drive East
Marlton, NJ 08053
(212) 397-1000 (main)
(856) 988-5574 (local)
(*Counsel for Plaintiffs*)

CONSTANTINE J. PASSODELIS, ESQUIRE
Email: dpassodelis@jonespassodelis.com
MARIE MILIE JONES, ESQUIRE
Email: mjones@jonespassodelis.com
JonesPassodelis, PLLC
Gulf Tower, Suite 3410
707 Grant Street
Pittsburgh, PA 15219
(412) 315-7272
(412) 315-7273 – FAX

AND

Robert E. Johnston, Esquire
Email: RJohnston@Hollingsworthllp.com
Donald R. McMinn, Esquire
Email: DMcminn@Hollingsworthllp.com
Andrew L. Reissaus, Esquire
Email: AReissaus@Hollingsworthllp.com
Hollingsworth LLP
1350 I Street Northwest
Washington, District of Columbia 20005
(202) 898-5800
(202) 682-1639

Counsel for Defendant Novartis Pharmaceuticals Corporation

2. Set forth the general nature of the case (patent, civil rights, anti-trust, class action, etc.):

This is a product liability lawsuit in which plaintiffs' claims relate to injuries allegedly caused by Tasigna® – a cancer medication made by Novartis Pharmaceuticals Corporation (“NPC”) that is FDA-approved to treat patients with Philadelphia chromosome positive chronic myeloid leukemia. NPC denies plaintiffs' claims.

3. Date Rule 26(f) Conference was held, the identification of those participating therein and the identification of any party who may not yet have been served or entered an appearance as of the date of said Conference:

On May 20, 2020 at 11:30 a.m., the parties conducted a 26(f) conference via telephone and the participants were: Christopher R. LoPalo and W. Steven Berman and on behalf of the plaintiffs, and Constantine J. Passodelis, Francesca M. Miller, Donald R. McMinn, and Douglas Jackson-Quzack on behalf of NPC.

4. Date of Rule 16 Initial Scheduling Conference as scheduled by the Court: (Lead Trial Counsel and unrepresented parties shall attend the Rule 16 Initial Scheduling Conference with their calendars in hand for the purpose of scheduling other pre-trial

events and procedures, including a Post-Discovery Status Conference; Counsel and unrepresented parties shall attend the Rule 16 Initial Scheduling Conference prepared to discuss the anticipated number of depositions and identities of potential deponents and the anticipated dates by which interrogatories, requests for production of documents and requests for admissions will be served):

Rule 16 Initial Scheduling Conference is scheduled to be held on June 3, 2020 at 9:30 a.m.

- 5. Identify any party who has filed or anticipates filing a dispositive motion pursuant to Fed. R. Civ. P. 12 and the date(s) by which any such anticipated motion may be filed:**

NPC filed an Answer to Complaint and Affirmative Defenses on April 23, 2020. *See* (ECF No. 6).

- 6. Designate the specific Alternative Dispute Resolution (ADR) process the parties have discussed and selected, if any, and specify the anticipated time frame for completion of the ADR process. Set forth any other information the parties wish to communicate to the court regarding the ADR designation**

The parties have agreed to participate in mediation, as set forth in the parties' ADR stipulation.

- 7. Set forth any change that any party proposes to be made in the timing, form or requirements of Fed. R. Civ. P. Rule 26(a) disclosures, whether such change is opposed by any other party, whether any party has filed a motion seeking such change and whether any such motion has been ruled on by the Court:**

The parties do not anticipate any change to the timing, form or requirements of Fed. R. Civ. P. Rule 26(a) disclosures at this time.

- 8. Subjects on which fact discovery may be needed.** (By executing this report, no party shall be deemed to (1) have waived the right to conduct discovery on subjects not listed herein or (2) be required to first seek the permission of the Court to conduct discovery with regard to subjects not listed herein):

The parties anticipate discovery to include, but not limited to, the following subjects:

- Fact discovery relating to plaintiffs, including medical, employment, and behavioral history;
- Corporate discovery related to NPC's product, Tasigna®, such as the FDA regulatory file, including the New Drug Application;
- Expert discovery, including on general and specific causation; and
- Depositions of fact and expert witnesses.

9. Set forth suggested dates for the following (The parties may elect by agreement to schedule a Post-Discovery Status Conference, as identified in Paragraph 12, below, at the conclusion of Fact-Discovery rather than at the conclusion of Expert Discovery. In that event, the parties should provide suggested dates only for the events identified in sub-paragraphs 9.a through 9.e, below. The parties shall provide such information even if dispositive motions pursuant to Fed. R. Civ. P. 12 have been or are anticipated to be filed. If there are dates on which the parties have been unable to agree, set forth the date each party proposes and a brief statement in support of each such party's proposed date. Attach to this report form a proposed Court Order setting forth all dates agreed to below and leaving a blank for the insertion of a date by the Court for any date not agreed to):

Parties' Preliminary Statement Regarding Proposed Dates:

The parties respectfully request that the discovery deadlines in this case be based on trial occurring within two years after the initial case management conference, rather than the timeframe contemplated by the Court's case management order template. As an initial matter, it is unclear at this stage the scope of the discovery that plaintiffs may seek from NPC. Plaintiffs will likely seek to depose numerous current and former employees of NPC and the production of millions of pages of NPC documents. Although plaintiffs' counsel will have access to discovery taken in two prior cases involving Tasigna®, plaintiffs have indicated an intent to take additional discovery. Moreover, NPC is a defendant in 30 cases in federal courts and in New Jersey state court involving claims arising from treatment with NPC's product, Tasigna®, and the number of cases likely will continue to grow. The parameters and scope of discovery of NPC in these matters merits informal coordination in terms of protocols such as search terms and custodians.

The parties have started these discussions, but it will take time to confer and reach agreements about these issues. Plaintiffs also agree that informal coordination may provide efficiencies and reduce or eliminate duplication during discovery, especially concerning depositions of corporate representatives and witnesses, where practicable.

Importantly, this case implicates an array of scientific, medical, and regulatory issues that will be the subject of wide-ranging expert reports and testimony. NPC anticipates that the parties will designate a dozen, or perhaps more expert witnesses (six per party, or more), which does not include the numerous treating physicians who will need to be deposed. NPC expects that it will seek evidentiary hearings on its *Daubert* motions that will challenge the admissibility of plaintiffs' experts.

Additionally, discovery in this case includes the need to obtain copies of medical records from Mr. Buzzelli's healthcare providers. The records collection process takes time, and is iterative in nature. As each set of records is received, they must be reviewed, and follow-up undertaken, to ensure that the provider has produced a complete set of records. Also, review of collected records inevitably leads to the identification of additional healthcare providers or locations of treatment, and new requests must be made to collect those. Although the parties will work diligently to collect records, often facilities take significant amounts of time to respond to requests.

COVID-19 enhances the challenge associated with records collection. The process will likely require additional time because of the burden that the pandemic has put on healthcare providers and the possibility that offices, due to social distancing considerations, are closed or will not have extra staff available on-site to locate and copy needed records. Similarly, witness preparation schedules will be disrupted by various stay at home orders; while some of those

orders are beginning to be lifted or relaxed, substantial restrictions on travel (including in New Jersey, where NPC is located) are expected to continue for months and there will be 14-day quarantine requirements if individuals travel to certain areas. There also is the possibility of restrictions being reinstated in the fall, when many models are expecting a rise in the number of infections. Given the unprecedented situation and the logistical hurdles surrounding COVID-19, NPC requests that the Court set a schedule that builds in additional time for the parties to work around these issues.

Against this backdrop, the parties have provided proposed deadlines below.

- a. Date(s) on which disclosures required by Fed. R. Civ. P. 26(a) have been or will be made:** June 17, 2020
- b. Date by which any additional parties shall be joined:** July 12, 2020.
- c. Date by which the pleadings shall be amended:** July 12, 2020.
- d. Date by which fact discovery should be completed:** August 3, 2021
- e. If the parties agree that discovery should be conducted in phases or limited to or focused on particular issues, identify the proposed phases or issues and the dates by which discovery as to each phase or issue should be completed:**

The parties are not proposing phased discovery with the exception of expert discovery to be completed after the close of fact discovery as set forth below.

- f. Date by which plaintiff's expert reports should be filed:** October 4, 2021
- g. Date by which depositions of plaintiff's expert(s) should be completed:** December 20, 2021
- h. Date by which defendant's expert reports should be filed¹:** November 4, 2021
- i. Date by which depositions of defendant's expert(s) should be completed:** January 20, 2022.

¹ While the parties would prefer not to file their expert reports as they will contain confidential and proprietary information, they anticipate seeking a Protective Order to maintain the confidentiality of plaintiff's and defendant's expert reports required to be filed. Please see paragraph 13.

j. **Date by which third party expert's reports should be filed:** N/A

k. **Date by which depositions of third party's expert(s) should be completed:** N/A

10. If the parties agree that changes should be made to the limitations on discovery imposed by the Federal Rules of Civil Procedure or Local Rule or that any other limitations should be imposed on discovery, set forth such changes or limitations:
No changes except as set forth in paragraph 13.

11. Please answer the following questions in regard to the discovery of electronically stored information (“ESI”):

a. **ESI.** Is either party seeking the discovery of ESI in this case?
 Yes No [If “No,” skip to sub-part (e) below.]

b. **ESI Discovery Plan.** The parties have reviewed and discussed the Court’s Checklist for Rule 26(f) Meet and Confer Regarding Electronically Stored Information set forth in “[Appendix LCvR 26.2.C-CHECKLIST](#)” to the Local Rules and:

Have agreed that, in light of the facts and issues in this case, there is no need to complete an ESI discovery plan, and will conduct ESI discovery by _____

_____.

Have developed an ESI discovery plan (as attached).

Will have an ESI discovery plan completed by: July 10, 2020

NOTE: At the direction of the Court, parties may be required to submit a draft of the Stipulated Order re: Discovery of Electronically Stored Information for Standard Litigation set forth in “[Appendix LCvR 26.2.E-MODEL ORDER](#)” to the Local Rules, to address specific issues relative to the parties’ exchange of electronic discovery and ESI. If the parties are unable to do so, they should advise the Court promptly.

c. **Preservation.** Have the parties agreed on any protocol for the preservation of electronic data and/or potentially relevant ESI?
 Yes No

d. **ADR.** Does any party believe that the exchange of ESI is necessary prior to conducting meaningful Alternative Dispute Resolution (“ADR”) in this case?

Yes No

e. **Clawback Agreement.** The parties have reviewed F.R.C.P. 26(b)(5), F.R.E. 502 and LCvR 16.1.D, Procedures Following Inadvertent Disclosure, and:

- Request the Court enter an Order implementing Federal Rule of Evidence 502(d) such as the model Order set forth in “Appendix LCvR 16.1.D” to the Local Rules and filed with this Report.
- Have agreed on alternate non-waiver language, which either is or will be incorporated within the ESI discovery plan.
- Are unable to agree on appropriate non-waiver language.

f. **EDSM and E-Mediator.** Does any party believe that the appointment of an E-Discovery Special Master (“EDSM”) or E-Mediator would help resolve ESI discovery issues in this case? For further information, see the Court’s official website at <http://www.pawd.uscourts.gov>.

Yes No

g. **Other.** Identify all outstanding disputes concerning any ESI issues:

12. Set forth whether the parties have elected to schedule the Post-Discovery Status Conference following the completion of Fact Discovery or Expert Discovery; in either event the parties shall be prepared at the Post-Discovery Status Conference to discuss and/or schedule the following: (The parties are *not* required during their Rule 26(f) Conference to consider or propose dates for the items identified below. Those dates will be determined, if necessary, at the Post-Discovery Status Conference. Lead trial counsel for each party and each unrepresented party are required to attend the Post-Discovery Status Conference with their calendars in hand to discuss those items listed below that require scheduling. In addition, a representative with settlement authority of each party shall be required to attend; representatives with settlement authority of any insurance company providing any coverage shall be available throughout the Conference by telephone):

- a. Settlement and/or transfer to an ADR procedure;
- b. Dates for the filing of expert reports and the completion of expert discovery as itemized in sub-paragraphs 9.f. through 9.k., above, if the parties elected to defer such discovery until after the Post-Discovery Status Conference;

- c. **Dates by which dispositive motions pursuant to Fed. R. Civ. P. 56, replies thereto and responses to replies should be filed;**
- d. **Dates by which parties' pre-trial statements should be filed;**
- e. **Dates by which *in limine* and *Daubert* motions and responses thereto should be filed;**
- f. **Dates on which motions *in limine* and *Daubert* motions shall be heard;**
- g. **Dates proposed for final pre-trial conference;**
- h. **Presumptive and final trial dates.**

The parties have elected to schedule the Post-Discovery Status Conference following the completion of Expert Discovery, and request the Court conduct an evidentiary hearing related to the expected *Daubert* issues in this case.

13. Set forth any other order(s) that the parties agree should be entered by the court pursuant to Fed. R. Civ. P. 16(b) or 26(c):

As this time, NPC has presented a proposed stipulated confidentiality and protective order (“Protective Order”) related to the disclosure of information in this case (Ex. 1). Such orders are typical and customary in product liability cases, especially those involving regulated pharmaceutical products. NPC’s proposed Protective Order is substantially similar to protective orders that were developed in two prior cases involving the same product at issue in this case. There were more than 10.6 million pages of searchable documents produced in those cases that will be made available to plaintiff once the parties in this case enter into a substantially similar Protective Order. Additionally, the parties anticipate seeking protection from disclosure of confidential and proprietary information contained in their respective expert reports through the filing of a Protective Order. Plaintiffs note that they may request the right to propound additional

interrogatories but cannot make that determination prior to Rule 26 disclosures, including access to discovery responses from other litigations.

14. Set forth whether the parties anticipate that the court may have to appoint a special master to deal with any matter and if so, specify the proposed role of any such master and any special qualifications that such master may require to perform such role:

No, the parties do not anticipate the appointment of a special master in this case.

15. If the parties have failed to agree with regard to any subject for which a report is required as set forth above, except for proposed dates required in paragraph 9, above, briefly set forth the position of each party with regard to each matter on which agreement has not been reached:

N/A

16. Set forth whether the parties have considered the possibility of settlement of the action and describe briefly the nature of that consideration:

The parties have agreed to mediation and will participate in good faith.

Respectfully submitted,

S/W. Steven Berman
Counsel for Plaintiffs

S/Constantine J. Passodelis
Counsel for Novartis Pharmaceuticals Corporation